IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Michael Kennelly M.D.)

The plaintiffs filed their Notice of Adoption of Prior Daubert Motion of Michael Kennelly, M.D. for Waves 4 and 5 cases ("Notice") [ECF No. 4543] in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, on September 27, 2017. The plaintiffs attached as exhibits to their Notice a motion [ECF No. 4543-1], memorandum in support [ECF No. 4543-2], and reply brief [ECF 4543-3], which plaintiffs seek to adopt and incorporate as their briefing for Waves 4 and 5. Defendants also adopted and incorporated by Notice of Adoption of C.R. Bard, Inc.'s Prior Brief in Opposition to Plaintiffs' *Daubert* Motion to Exclude Opinions of Dr. Michael Kennelly for Wave 4 and Wave 5 cases, a brief in response to Plaintiffs' Motion. [ECF No. 4641]. The court construes the plaintiffs' Notice as a motion. As such, the Notice is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses, and replies were to be filed in the individual member cases. To the extent that an

expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

Before plunging into the heart of the Motion, to clarify the record, I am compelled to comment on the manner in which the parties filed the instant *Daubert* motion and response in opposition. Similar to other *Dauberts* filed in the main MDL, the plaintiffs filed the instant motion as a "Notice," adopting and incorporating the entirety of a motion and its corresponding papers filed in a previous case before the court. Defendant C. R. Bard, Inc. ("Bard"), likewise, filed its opposing briefs in conjunction with a similar "Notice." The parties then attached the substance of their briefs, i.e., the supporting or opposing memorandum of law, as an exhibit to their respective Notice. So, for example, the plaintiffs attach the memorandum in support of their *Daubert* motion as "Exhibit 1" to their Notice. The plaintiffs also integrate into Exhibit 1 vital supporting papers, such as the deposition transcripts demarcated rather confusingly within Exhibit 1 as "Exhibit A," forming one large document. With this in mind, the court turns its attention to the present dispute.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R.

Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct" – "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has

been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted). At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

III. Discussion

Dr. Michael Kennelly is a physician who specializes in the diagnosis and treatment of urinary incontinence and female pelvic floor disorders. Bard offers Dr. Kennelly as an expert witness on the general safety and effectiveness of the Align. The plaintiffs move to exclude some of Dr. Kennelly's opinions on the grounds that his applied methodology is unreliable. I address the plaintiffs' objections in turn.[1]

A. Opinions Based on Data Derived from Ethicon's TVT-Slings

Dr. Kennelly admits that his opinions, in part, rely on the Cochrane Review, which primarily focuses on data collected from the TVT sling, a product produced by another manufacturer. In the plaintiffs' view, this data on the TVT cannot form a reliable basis for Dr. Kennelly's opinion on the Align, given that the products have "different thickness and pore sizes." Pls.' Mot. to Exclude Op. & Test. of Dr. Michael Kennelly & Br. in Supp., at 7 [ECF No. 4543-1]. I disagree. *Daubert* requires an expert's opinion to have "a valid scientific connection to the pertinent inquiry." *Daubert*, 509 U.S. at 591-92. Here, Dr. Kennelly has established this requisite connection between the Cochrane Review and his opinions on the Align.

[1] Throughout their briefing, the plaintiffs "incorporate" the arguments set forth in their Omnibus Motion to Exclude Certain General Opinions and Testimony of Bard's Physician Experts. A blanket motion to exclude broad categories of expert testimony is inappropriate and contrary to the established framework of the Federal Rules of Evidence, which contemplate the evaluation of expert testimony on an individualized basis. I accordingly limit my review of the instant motion to the plaintiffs' arguments contained in the accompanying memorandum, which concerns the testimony of Dr. Kennelly specifically.

First, as Dr. Kennelly explains, the TVT and the Align are "very similar" for all purposes relevant to his opinion. *See* Pls.' Mot. to Exclude Op. & Test. of Dr. Michael Kennelly & Br. in Supp., Ex. A ("Pls.' Kennelly Dep.") at 169:9-11 [ECF No. 4543-1]. With respect to structure and design, both products are made of "the same Type 1 macroporous polypropylene," *id.* at 169:23-24; "have the same indications for stress urinary incontinence," *id.* at 169:24-25; and are "placed in the same format." *Id.* at 171:25-172:2. Dr. Kennelly acknowledges the products' differences, but explains that they are minor and do not impact his conclusions. *See id.* at 169:22–171:2 (concluding that the Cochrane Review still provides relevant data for the Align, despite product differences). Second, from his extensive experience as a pelvic surgeon, Dr. Kennelly testified that the products operate similarly. *See id.* at 170:22–171:2 (explaining that in his "view as a practicing clinician who has been doing this for over 10 to 14 years," the products "are really the exact same type of device"). Dr. Kennelly has implanted approximately 1,000 midurethral slings over the past twenty-two years. *See* Def.'s Br. in Opp'n to Pls.' Daubert Mot. to Exclude Ops. of Dr. Michale Kennelly, Ex. C ("Def.'s Kennelly Dep.") at 74:7 [ECF No. 4641-2]. In over 90% of those procedures, he used slings made of synthetic mesh, *id.* at 74:11-13, and he has implanted the Align specifically over 100 times. *Id.* at 98:6-8. Importantly, Dr. Kennelly has "utilized and investigated a variety of materials (autologous, allograft, xenograft, and synthetic) and techniques for sling placement," allowing him to compare their performance to that of the Align. *See* Pls.' Mot. to Exclude Op. & Test.

of Dr. Michael Kennelly & Br. in Supp., Ex. C ("Dr. Kennelly's Expert Report") at 11 [ECF No. 4543-1].

Based on the described similarities between the products and his experience with various pelvic repair procedures, Dr. Kennelly concludes that the Cochrane Review, though based on TVT data, is reasonably applicable to midurethral slings in general, including the Align. *See* Pls.' Kennelly Dep., at 171:15-22. Because Dr. Kennelly has established this reasonable connection between the products, I do not find his consideration of the Cochrane Review fatal to his opinions on the safety and efficacy of the Align.

In addition to the Cochrane Review, Dr. Kennelly considered four studies specific to the Align when reaching his opinions. In their reply briefing, the plaintiffs criticize these studies, suggesting that they do not support the efficacy or safety of the Align. Primarily, the plaintiffs point to the studies' small sample sizes and Dr. Kennelly's concession that the data on the Align is "not robust." *See* Pls.' Reply in Supp. of Mot. to Exclude the Ops. & Test of Dr. Michael Kennelly ("Reply re: Kennelly") at 2-3 [ECF No. 4543-3]. That more research should be done on the Align does not mean that the current research is unreliable. The four studies cited by Dr. Kennelly applied the scientific method, underwent the peer-review process, and were ultimately published in urogynecological journals. These factors suggest that the studies are reliable. *See Daubert*, 509 U.S. at 594-94 (holding that in reviewing expert testimony, the "overarching subject is the scientific validity"); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (explaining that whether a theory

has been tested and whether it has been subjected to peer review, among other considerations, "may bear on a judge's determination of the reliability of an expert's testimony").

Taken together, Dr. Kennelly's experience, the TVT data, and the available Align data establish a reliable scientific basis for his opinion that that the Align is safe and effective. The plaintiffs' remaining objections on this matter go to credibility, not admissibility, and are better suited for cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). Therefore, the plaintiffs' motion on this point is **DENIED**.

B. Opinions that Mesh Does Not Shrink or Contract

Dr. Kennelly also opines that polypropylene mesh does not shrink. The plaintiffs contend that Dr. Kennelly's failure to consider contrary literature renders this opinion unreliable. The reliability of an expert's opinion comes into question when he has not acknowledged or accounted for science that refutes his position. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) ("[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable."). Here, however, Dr. Kennelly has acknowledged other contrary articles and has explained his reasons for finding them unpersuasive:

> Q: Have you considered references that disagree with your conclusion that mesh does not shrink or contract?

> A: Yes. And some of the studies have been more animal-based studies. I think the information that was there was also shorter-term studies as opposed to longer-term.

Def.'s Kennelly Dep. at 212:410. Dr. Kennelly also explains that the authors of these contrary articles are misinterpreting the effect of the mesh "conforming" to the trocar as mesh shrinkage. *Id.* at 212:22–213:4. Then, when asked about two specific articles in favor of mesh shrinkage, Dr. Kennelly states specifically his reasons for his disagreement. *See id.* at 215:18–216:13 (discussing the Feiner, Maher study); *id.* at 220:22–221:12 (discussing the International Urogynecological Association presentation). From this testimony, I am persuaded that Dr. Kennelly considered and accounted for articles contrary to his position. The plaintiffs' remaining arguments that Dr. Kennelly's opinions are "conflicting" go to the weight of his opinion and can be raised during cross-examination. This part of the plaintiffs' motion is therefore **DENIED**.

C. Opinions that Mesh Does Not Degrade

The plaintiffs next challenge Dr. Kennelly's opinion that polypropylene mesh does not degrade in the body. In the plaintiffs' view, Dr. Kennelly bases the entirety of this opinion on his personal experience and data from products other than the Align, and consequently, it lacks reliability. I am not persuaded by this argument. As explained above,[2] Dr. Kennelly has connected the data from other Type 1 polypropylene products to the issues in this case such that his reliance on this data is not improper under *Daubert*. Furthermore, although an "I-haven't-seen-

[2] *See supra* Section III.A.

degradation-so-it-doesn't-occur" opinion would likely raise reliability concerns, Dr. Kennelly has gone beyond his personal experience to reach his opinion on mesh degradation in this case. He has considered the available clinical evidence, the properties of the material, and its medical applications. *See* Dr. Kennelly's Expert Report, at 13-14. In addition, he has reflected on his education and training, *see* Pls.' Kennelly Dep., at 233:8-15 (discussing the meetings and presentations he has attended on mesh degradation), and reviewed scientific literature on the degradation of Type 1 polypropylene mesh, both favorable and unfavorable to his opinion. *See* Def.'s Br. in Opp'n to Pls.' Daubert Mot. to Exclude Ops. of Dr. Michale Kennelly, Ex. D, at 1009:16-19 [ECF No. 4641-2].

In their reply briefing, the plaintiffs point to a handful of articles that Dr. Kennelly did not specifically mention in his expert report. *See* Reply re: Kennelly, at 8-10. Nothing in *Daubert*, however, requires an expert to consider every single article on a topic in order to be admitted as an expert. *See Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989) ("One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an opinion."). Therefore, I decline to exclude Dr. Kennelly solely for failing to comment on specific articles in his report. *See id.* ("Generally, the test for exclusion is a strict one, and the purported expert must have neither satisfactory knowledge, skill, experience, training nor education on the issue for which the opinion is proffered."). Thus, the plaintiffs' motion on this matter is **DENIED**.

D. Opinions on Complication Rates

The plaintiffs raise similar objections to Dr. Kennelly's opinion that "for most urologists and urogynecologists, [midurethral mesh sling systems have] low morbidity and no or few complications." Dr. Kennelly's Expert Report, at 12. First, the plaintiffs claim that this opinion is based upon the information in the Cochrane Review and like statements from other organizations that concern TVT data rather than Align data. I have disposed of this argument above. *See supra* Section III.A. Second, the plaintiffs again contend that Dr. Kennelly's opinion is unreliable because he failed to account for two studies: the Ugurlucan and the Madsen study, both which report high failure rates. As Bard explains, however, Dr. Kennelly did acknowledge and distinguish these studies. *See* Pls.' Kennelly Dep., at 183:10–184:19 (discussing the Ugurlucan study); *id.* at 185:9–186:8 (discussing the Madsen study)). Accordingly, the plaintiffs' motion concerning Dr. Kennelly's opinions on complication rates is **DENIED**.

E. Opinions Concerning the MSDS

The plaintiffs next argue that Dr. Kennelly is not qualified to offer any opinions related to the MSDS. Dr. Kennelly's opinion, in short, is that he has "seen no evidence that there is any scientific basis supporting the medical application caution language in the [MSDS]." Dr. Kennelly's Expert Report, at 15). *Daubert* bars expert testimony based on "belief or speculation." *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999). Dr. Kennelly, who has no knowledge about a manufacturer's considerations when drafting an MSDS, attempts to opine that because he did not see any evidence suggesting the MSDS has scientific roots, none exists. Such a

speculative leap is improper for expert testimony. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."). Therefore, the plaintiffs' motion on this point is **GRANTED**, and this opinion is **EXCLUDED**.

F. Opinions Concerning the Align's Instructions for Use ("IFU")

Dr. Kennelly also opines that the "Bard Align IFU adequately and appropriately warned implanting surgeons about the risks of using the Align." Dr. Kennelly's Expert Report, at 30.[3] The plaintiffs contend that Dr. Kennelly lacks the expertise to opine on the requirements of a product's IFU. Although Dr. Kennelly has no experience with drafting IFUs, he has demonstrated experience with the Align and the risks associated with its use. *See supra* Section III.A. Based on this experience, I find him qualified to testify about whether the risks he perceives are in fact warned about in the IFU. The plaintiffs' contention that Dr. Kennelly did not review the relevant IFU version—the 2006, 2008, or 2010 Align IFU—is better suited for cross-examination.

However, Dr. Kennelly's opinion testimony on the IFU must stop here. A doctor who has no background in the requirements of an IFU is not qualified to opine that it "*adequately and appropriately*" warns of the risks, *see* Dr. Kennelly's Expert Report, at 29-30 (emphasis added)), merely because it mentions risks he personally knows about or has observed in his practice. *See, e.g.*, *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 584 (S.D. W. Va. 2014) (excluding an urologist as unqualified to

[3] Note that "IFU" is synonymous with "DFU."

opine that a DFU "adequately warned" of "all [] potential complications"). Accordingly, without additional expertise in the specific area of product warnings, these opinions on the IFU are **EXCLUDED**. The plaintiffs' motion on this point is thus **DENIED in part** and **GRANTED in part**.

G. Opinions Concerning the FDA

Dr. Kennelly summarizes the FDA's "stance on mesh slings" in his expert report, and the plaintiffs move to exclude this discussion on Rule 403 grounds. *See* Dr. Kennelly's Expert Report, at 31-33. I agree that this testimony is inadmissible. This case concerns state tort law, not federal regulatory law, and as such, a recap of an FDA panel's findings will not "help the trier of fact to understand the evidence or to determine a fact in issue," Fed. R. Evid. 702. Indeed, discussion of the FDA panel's position through an expert witness could lead to more confusion than enlightenment. The jurors may erroneously believe that the FDA's "stance" relates to the validity of the plaintiffs' state law tort claims, or they may attach undue significance to the FDA panel's determination. Therefore, finding the probative value of this testimony to be substantially outweighed by the risk of misleading the jury, I **EXCLUDE** Dr. Kennelly's opinions and testimony related to the FDA and the FDA panel's assessment of mesh slings. *See* Fed. R. Evid. 403; *see also Daubert*, 509 U.S. at 595 (emphasizing that courts must keep the other evidentiary rules in mind when evaluating the admissibility of expert opinions because expert evidence can be "both powerful and quite misleading"). The plaintiffs' motion on this point is therefore **GRANTED**.

IV. Conclusion

For the reasons stated above, the court **ORDERS** that the plaintiffs' Notice of Adoption of Prior Daubert Motion of Michael Kennelly, M.D. for Waves 4 and 5 cases [ECF No. 4543], which has been construed by this court as a motion, is **GRANTED in part** and **DENIED in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 5, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.